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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CONNETICS CORP. SECURITIES LITIGATION

Case No. C 07-02940 SI

NOTICE OF MOTION AND MOTION TO DISMISS PLAINTIFF'S AMENDED CONSOLIDATED CLASS ACTION COMPLAINT BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS, LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G. WIGGANS; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Date: October 19, 2007
Time: 9:00 a.m.
Dept: Courtroom 10, 19th Floor
Judge: Honorable Susan Illston

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STATUTES

NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE that on October 19, 2007, at 9:00 a.m. or as soon thereafter as counsel may be heard, in the Courtroom of the Honorable Susan Illston, located at the United States District Court, 450 Golden Gate Avenue, San Francisco, California, defendants Connetics Corp. ("Connetics" or the "Company"), John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans will and hereby do move for an order dismissing the Amended Consolidated Class Action Complaint ("Amended Complaint" or "AC") in this action. Defendants make this motion pursuant to the Private Securities Litigation Reform Act of 1995 ("Reform Act") and Federal Rules of Civil Procedure 12(b)(6) and 9(b) on the grounds that plaintiff has failed to plead facts sufficient to state a claim against them. The motion is based upon the following Memorandum of Points and Authorities, the Request For Judicial Notice In Support Of Defendants' Motion To Dismiss Plaintiff's Amended Consolidated Class Action Complaint, the Declaration of Christopher J. Steskal, the pleadings and records on file herein, and such other matters as may be presented to the Court.

ISSUES TO BE DECIDED (CIVIL LOCAL RULE 7-4(A)(3))

1. Whether plaintiff's Section 10(b) claim should be dismissed because:
   - (a) plaintiff sold all of its Connetics shares before June 13, 2005, when the putative "fraud" concerning Velac (a drug under development) was revealed, and therefore suffered no loss and has no standing;
   - (b) the forward-looking statements attributed to defendants are protected by the Reform Act's "safe harbor," and even if not protected, plaintiff has failed to plead specific facts showing actual knowledge of falsity;
   - (c) plaintiff has failed to allege with particularity the reasons why each statement is purportedly misleading;
   - (d) plaintiff has failed to plead facts giving rise to a strong inference of scienter; and
   - (e) plaintiff has failed to plead loss causation.
2. Whether plaintiff's claim under Section 20A should be dismissed because:
   - (a) plaintiff has not shown an underlying violation of Section 10(b);

(b) plaintiff has failed to plead particularized facts demonstrating that any defendant sold Connetics stock on the basis of material non-public information; and

(c) plaintiff has failed to plead that it traded "contemporaneously" with each defendant.

3. Whether plaintiff's Section 20(a) claim should be dismissed because plaintiff has failed to allege that defendants committed a primary violation of Section 10(b) or were responsible for or controlled the specific transaction or activity upon which the claim is predicated.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiff's case against Connetics and several of its senior executives (Dr. Krochmal, Mr. Wiggans, Mr. Vontz, and Mr. Higgins) is premised on the allegation that they all knew as early as June 2004 that one of the drugs Connetics was developing, Velac gel, "stood virtually no chance of being approved." AC ¶ 1. Nevertheless, according to plaintiff, defendants proceeded to move ahead full speed thereafter by pursuing time consuming and expensive approval from the FDA, hiring and training dozens of sales people in anticipation of approval, spending millions of dollars in milestone payments to the licensor of the drug, and preparing commercial operations to manufacture, distribute, and sell Velac. Plaintiff asserts that defendants pursued all of these knowingly pointless efforts all the while making false optimistic statements with the secret intent of misleading investors.

Not surprisingly, this story is not supported by particularized factual pleadings. Instead, despite 372 paragraphs and over 110 pages designed to create the illusion of specificity, plaintiff has alleged nothing more than impermissible "fraud by hindsight" by attempting to recast the unfortunate story of an unsuccessful effort to obtain approval of a new drug into something nefarious. Although devoid of the concrete facts needed to plead securities fraud under the Reform Act, plaintiff's case is revealing in at least one respect: plaintiff was ***not*** a Connetics shareholder when Connetics announced on June 13, 2005 that the FDA had issued a "non-approvable" letter concerning Velac, the event which allegedly "revealed" the fraud. Thus,

putting aside other deficiencies, plaintiff could not have suffered any cognizable loss associated with Velac, and it therefore lacks standing to sue.[1]

Plaintiff's claim that defendants engaged in a "massive financial fraud" is equally unavailing. Connetics voluntarily announced in May 2006 that it had uncovered errors in its prior calculation of reserves for returns, rebates, and chargebacks, and would therefore be restating its 2005 financial statements (and possibly earlier periods) by $8-9 million. Two months later on July 25, 2006, shortly after the class period ended, Connetics completed the restatement, which resulted in a total of just $1.1 million in adjustments in 2004 and $7.9 million in 2005 (with restated revenues of $143.2 million and $176.3 million, respectively). Although plaintiff's overheated rhetoric alleges fraud, it seems to believe that the mere fact of a restatement is enough to plead a strong inference of scienter with respect to Connetics and its officers. That simply is not the law. What the law does require is particularized factual allegations that give rise to a strong, "cogent and compelling" inference that each defendant *knew* (or was deliberately reckless in not knowing) that Connetics' reserves were incorrect at the time the Company issued its financial statements. Such allegations are entirely absent here.

For these reasons, and the other reasons detailed herein, this action should be dismissed.

II. BACKGROUND

A. Connetics And The Moving Defendants

Connetics is a specialty pharmaceutical company that develops and markets drugs for the dermatological market. AC ¶¶ 18, 35. These are drugs designed to treat skin conditions, such as psoriasis, seborrheic dermatitis, and acne. *Id.* Connetics was founded in 1993 and went public in 1996. It has experienced considerable growth in the ensuing periods, with annual net revenue growing from $40.7 million in 2000 to over $176 million by the year ended December 31, 2005. In December 2006, it was acquired by Stiefel Laboratories, the world's largest independent drug company specializing in dermatology, in a $640 million merger.

[1] Despite the so-called "fraud" revealed on June 13, 2005, plaintiff decided to buy shares thereafter even though Connetics was run by precisely the same management team. Needless to say, the Amended Complaint does not even try to explain why plaintiff would invest in a company that had just revealed a "fraud."

During the purported class period from January 27, 2004 through July 9, 2006, Connetics offered four products: Luxíq, OLUX, Evoclin, and Soriatane. *Id.* ¶ 253. It reported (on a restated basis) net revenues of $143.2 million and $176.3 million, and net income of $17.9 million and $26.1 million in 2004 and 2005, respectively. *Id.* ¶¶ 135-36. In addition to these products, Connetics also had several in its development pipeline, including Velac gel. *Id.* ¶ 2.

Tom Wiggans was Connetics' Chief Executive Officer and a member of the Board of Directors. *Id.* ¶ 19. Gregory Vontz served as the Chief Operating Officer and was promoted to President of Connetics in February 2005. *Id.* ¶ 20. John Higgins was the Executive Vice President, Finance and Administration and Corporate Development. *Id.* ¶ 21. He served as the Chief Financial Officer. *Id.* Dr. Lincoln Krochmal was the Executive Vice President of Research and Product Development. *Id.* ¶ 22.

B. The FDA Approval Process

Connetics' products are regulated by the Food and Drug Administration ("FDA"). *Id.* ¶ 36. Before a New Drug Application ("NDA") can be approved, the FDA generally requires both preclinical testing (*i.e.*, animal and lab studies) and clinical testing (*i.e.*, testing in humans). *Id.* The basic purpose of preclinical testing is to gather evidence on the potential new drug through laboratory experimentation and animal testing to determine if it is reasonably safe to begin preliminary trials in humans. Ex. 6, at 13 (Form 10-K); Ex. 7, at 17 (Form 10-K).[2] Clinical testing is designed to determine whether a drug is safe and effective in humans. *Id.* It is conducted in phases with increasingly larger volunteer patient pools. *Id.*; AC ¶ 36. The results of Phase III clinical trials, which is the final phase, are critical to the approval process and introduction of a new drug. Ex. 6, at 13 (Form 10-K); Ex. 7, at 17-18 (Form 10-K).

The FDA drug approval process is collaborative, with frequent communications between the FDA and a drug sponsor. *See, e.g.*, 21 C.F.R. §§ 312.47, 314.102; Ex. 28 (FDA, Manual of Policies and Procedures for the Center for Drug Evaluation and Research ("FDA Manual")

[2] All references to exhibits are to those attached to the Steskal Declaration and will appear in the form "Ex. ___." The Court may consider all such exhibits because they are either cited or quoted in the Amended Complaint or are otherwise subject to judicial notice. *See* Request For Judicial Notice, filed herewith.

§ 6010.5). This collaboration includes a "pre-NDA" meeting as well as a written communication from the FDA 74 days after submission of the NDA (the so-called "74-day" letter). *Id.* The pre-NDA meeting is held at the sponsor's request. It is designed to identify those studies that the sponsor is relying on for the NDA, to reach agreement with the FDA on statistical analysis protocol, and to uncover any major potential problems. 21 C.F.R. § 312.47(b)(2). The 74-day letter sets out any substantive deficiencies identified by the FDA's review team during their initial scrutiny of the NDA and is due 74 days after the filing date. *See* Ex. 28 (FDA Manual § 6010.5).

The FDA approval process is "lengthy, expensive and uncertain." Ex. 6, at 22 (Form 10-K); Ex. 7, at 31 (Form 10-K/A). According to the FDA's published data, approximately 40% of new drug candidates are not approved. Ex. 34, at 14, 16 (FDA's Center for Drug Evaluation and Research, Report to the Nation: 2005). Connetics periodically reported to investors on the regulatory status of its drugs in the development pipeline by disclosing certain milestone events, such as the initiation or completion of clinical trials or the submission of an NDA. Ex. 6, at 5-6 (Form 10-K); Ex. 7, at 9-11 (Form 10-K); Exs. 9, 11, 14, 17-18 (Forms 8-K). Consistent with industry norms, it was not Connetics' practice to disclose interim communications with the FDA. *Id.*; Ex. 1, at 6 (analyst call transcript).

Connetics repeatedly cautioned investors that regulatory approval was inherently uncertain, emphasizing that "successful product development in our industry is highly uncertain," and that "very few research products produce a commercial product." Ex. 6, at 23 (Form 10-K). It delineated a wide-range of risks, and regularly warned that "[w]e may spend a significant amount of money to obtain FDA and other regulatory approvals, ***which may never be granted***." *Id.* at 23 (emphasis added). Connetics specifically cautioned investors about "the market potential for Velac and the likelihood of approval of Velac" (Ex. 11 (Form 8-K)), warned that it "faces risks and uncertainties that . . . ***Velac may not be approved by the FDA in the timeframe projected, if at all***" (Ex. 12 (Form 8-K)), and that its efforts with respect to Velac "***may not result in the successful introduction of a new product***" (Ex. 6, at 5 (Form 10-K)).

C. Velac

Velac was "a novel, first in class, dual-active product combining the anti-inflammatory

and antibiotic effects of clindamycin with the beneficial effects of tretinoin." Ex. 8 (Form 8-K); *see also* AC ¶ 40. Clindamycin and tretinoin are among the most widely prescribed medications for acne, and Velac successfully combined these two active ingredients into a single formulation. *Id.*; Ex. 11 (Form 8-K). Connetics licensed the U.S. rights to Velac from Yamanouchi Europe B.V. in May 2002. AC ¶ 40; Ex. 8. At that time, Yamanouchi had already conducted clinical studies in Europe in more than 700 patients which demonstrated that Velac gel was both "safe and as effective as leading topical treatments." *Id.*

From May 2002, Connetics worked with the FDA to complete the testing required to file an NDA. *See* AC ¶¶ 36, 41-51. Connetics disclosed to investors both the status of the Velac NDA application and the results of its clinical trials:

- December 2002: Connetics initiated Phase III clinical testing involving two pivotal trials and two smaller supplemental clinical (*i.e.*, human) studies. *Id.* ¶ 44.
- Late 2003: Connetics completed enrollment in the clinical trials. *Id.* ¶ 45.
- March 2004: Connetics successfully completed its Phase III clinical trials. *See id.* ¶¶ 47-50. The Phase III human trials demonstrated that "Velac was safe and well tolerated, with the most commonly observed adverse effects being application site reactions (*e.g.*, burning, dryness, redness and peeling)." *Id.* ¶ 47.
- October 2004: The FDA accepted for filing the Company's NDA for Velac. Ex. 14 (Form 8-K).

In preparation for filing its NDA, Connetics also conducted a preclinical carcinogenicity study using transgenic or "Tg.AC" mice from January 2004 through June 2004. AC ¶¶ 52-55. According to the Amended Complaint, this study showed that "89 out of 160 of the mice (approximately 56%) treated with Velac developed cancerous skin tumors." *Id.* ¶ 56. As acknowledged in the Amended Complaint, however, the transgenic mouse model has significant limitations and does not always or reliably predict risks to humans. *Id.* (Tg.AC model fails to make "the correct calls" in 19 to 23% of cases).[3]

[3] Transgenic mice are genetically engineered so that tumors will arise more quickly. *See* Ex. 2, at 4 (Oct. 30, 2002 National Institutes of Health report), *cited in* AC ¶ 56. As such, these mice also have mutations that make them overly sensitive to certain chemicals, *i.e.*, the genetically altered mouse may develop a tumor due to its genetic make-up or the testing process that is not relevant to human use. Ex. 2, at 5; *see also id.* at 3 ("important issues of validation and standardization need further attention to permit their regulatory acceptance and use in human risk assessment.").

The Company was also aware of other products that had a similar positive finding in Tg.AC mice but nevertheless had been approved by the FDA. For example, benzoyl peroxide, a commonly used over-the-counter acne product and an ingredient in several prescription acne drugs, has labeling that notes a positive result in the transgenic mouse model. *See id.* ¶¶ 257, 261; Ex. 1, at 6 (analyst call transcript). One of these products is "BenzaClin," approved by the FDA in 2000, despite findings that "[b]enzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies" and that it "induced skin tumors in transgenic Tg.AC mice in a study using 20 weeks of topical treatment." Ex. 30, at 6 (BenzaClin labeling).

In light of this, even after the mouse study, Connetics believed that Velac could be approved by the FDA, and it acted in accordance with that belief. Among other things:

- Connetics incurred the substantial time and expense to prepare and file the NDA for Velac in August 2004. AC ¶ 63; Exs. 14-15 (Forms 8-K).
- Connetics paid an additional $3.5M to Yamanouchi as a milestone payment for its Velac license, triggered by filing the NDA. AC ¶¶ 217, 222; Ex. 6, at 34, 36 (Form 10-K).
- Connetics began preparing its commercial operations for the launch of Velac in 2005, including, for example, hiring more than 60 new sales professionals in January 2005 as part of a sales force expansion. AC ¶¶ 60, 202, 242, 244; Ex. 16 (Form 8-K).

Put simply, these actions confirm that Connetics was optimistic about the possibility of future approval of Velac and was making plans and spending money accordingly.

Indeed, despite the active and collaborative role of the FDA in the approval process, there is – and can be – no allegation that the FDA raised any concerns with respect to Velac or the Tg.AC mouse study anytime at or following the pre-NDA meeting or during the eight month period following the filing of the NDA. For example, there is no allegation that during the pre-NDA meeting (held before the NDA was filed in August 2004), the FDA told Connetics that the mouse study foreclosed the possibility of FDA approval of Velac. Nor is there any allegation that the FDA raised this issue in its 74-day letter sent to Connetics in November 2004. In fact, the Amended Complaint does ***not*** allege any facts suggesting that the FDA provided any indication to Connetics that the drug-approval process was not on track or that it had any negative views on Velac whatsoever in the many months that ensued, notwithstanding the FDA's broad powers to

comment, issue warning letters, or otherwise identify problems or deficiencies. *See* AC ¶ 39.

To the contrary, by the Amended Complaint's own admission, the first time the FDA expressed any concern was on April 13, 2005 (sixteen months into the putative class period). *Id.* ¶¶ 68-69. On that date, plaintiff alleges that there was a conference call in which the Executive Carcinogenicity Assessment Committee ("ECAC"), an advisory committee to the FDA, told Connetics that it was concerned that Velac "may be a tumor promoter or a carcinogen" based on the preclinical study and that "this is a serious issue for a topical product for the treatment of acne." *Id.* These allegations, however, fall far short of a final determination of non-approvability. All ECAC reports are advisory in nature and clearly state that they "***should not be interpreted by the sponsor as a measure of the approvability of their application***." Ex. 29 (FDA Manual § 7412.2).[4] Given that Velac was already supported by clinical trials (both in the U.S. and Europe), which plaintiff does not allege showed any indication that Velac posed a cancer risk to humans, and that the FDA had approved competing products by requiring positive Tg.AC results to be disclosed as a labeling matter (*e.g.*, benzoyl peroxide), Connetics remained optimistic about approval.

Nonetheless, in conjunction with Connetics' earnings release on April 26, 2005, Connetics promptly disclosed on Form 8-K and in a conference call the substance of its recent communications with the FDA to ensure that investors were aware of the concern expressed for the first time regarding the preclinical study:

> Over the past several weeks Connetics has been responding to the [FDA's] questions regarding the Company's New Drug Application ("NDA") for its product candidate Velac. As part of this dialogue, the Company recently received communications from the FDA indicating that the agency was interpreting some of the results of a pre-clinical study for Velac® Gel differently than the Company did in the NDA submission. The preclinical study in question involved a transgenic mouse model. In the study, there was a positive response to the product. The Company carefully analyzed the results with a panel of leading toxicologists and experts in this model. The experts advised the Company that the transgenic mouse model is known to have limitations, and the experts concluded that the positive response was the result of a limitation of the model. The advice of these experts is supported by other products which had a positive finding but were ultimately

[4] In fact, the very same FDA division director making the determination on Velac had previously approved dermatology products, such as Clobex, notwithstanding similar "safety" concerns of the FDA's advisors. *See* Exs. 32-33 (publicly available FDA director review and approval letter).

> approved based on additional work in other animal models. The Company is continuing its discussions with the FDA and expects to submit additional information which further supports the Company's original conclusion.

AC ¶ 257; *see also id.* ¶¶ 74-76; Ex. 17 (Form 8-K); Ex. 1, at 5-6 (analyst call transcript). In light of these disclosures, analysts projected delays of up to one year for Velac and/or reduced their revenue estimates. *See, e.g.*, Ex. 35 (Wachovia Capital projects delay of one year on April 26, 2005); Ex. 36 (Jeffries & Co. pushes launch date back six months); Ex. 37 (Summer Street projects delay of one quarter, with 12-18 months possible). Thus, the market understood from these disclosures that there was potentially a "serious issue" affecting the timing or approvability of Velac based on the FDA's recent comment.

After the close of market on Friday, June 10, 2005, and without prior notice by the FDA, Connetics received a non-approvable letter for Velac. AC ¶ 82. Before the market opened on June 13, Connetics disclosed that the FDA had not approved Velac. *Id.* ¶ 83. It also updated its 2005 guidance to exclude Velac in line with its prior statements. *Id.* ¶ 84.

D. Connetics' Sales Channels and Financial Statements

Connetics' FDA-approved products are not sold directly to patients or doctors, but instead are sold through wholesale distributors. *Id.* ¶ 101; Ex. 7, at 14 (Form 10-K/A). These distributors in turn sell to retail pharmacies. *Id.* During the class period, Connetics had agreements with three main distributors that accounted for the overwhelming majority of its sales – Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Corporation. *Id.* Under these agreements, these distributors agreed to provide inventory level reports which Connetics could use to forecast future demand for its products. *Id.*

The ability to forecast future demand is among the important variables in calculating reserves. *See* AC ¶¶ 107, 111; Ex. 21 (Form 8-K). Reserves are used to account for future estimated rebates, chargeback, and returns. AC ¶¶ 103-06. For example, when state and local Medicare programs purchase Connetics products, Connetics is required to pay a rebate under the Federal Medicaid Rebate program. *Id.* Although Connetics is not billed for the rebate until a patient purchases the drug from a pharmacy, the rebate obligation arose when Connetics sold the drug to the distributor, requiring Connetics to "predict" at the time of sale what percentage of

product will be purchased through the Medicare program. As another example, distributors and pharmacies have certain rights to return Connetics products that are within one year of their expiration date. *Id.* Connetics sets aside accruals and allowances to meet these obligations. *Id.* ¶ 107. As Connetics publicly disclosed, various other factors are also important in calculating the reserves, including timing and terms of plans under contract, time to process rebates, product pricing, sales volumes, units held by distributors, and prescription trends. Ex. 21 (Form 8-K); Ex. 5, at 39-40 (2003 Form 10-K); Ex. 6, at 37-38 (2004 Form 10-K).

On May 3, 2006, Connetics announced, among other things, that it would be restating its 2005 financial statements (and potentially earlier periods) by approximately $8-9 million due to the insufficiency of certain of its reserves. AC ¶ 121. Connetics explained that, in the course of preparing its financial statements for the first quarter of 2006, it had determined that its rebate and chargeback accruals had not been adequately capturing the full liability associated with product inventory in the distribution channel, and that its return accrual methodology contained errors that had resulted in misstatements. *Id.* ¶ 130; Ex. 21 (Form 8-K). Connetics' stock price did not decrease, but instead *increased* following this announcement. Ex. 41 (stock prices).

On July 25, 2006, after the class period, Connetics filed its amended Form 10-K for the year ended December 31, 2005 that included restated financials for 2004 and 2005. AC ¶ 130. Overall, the restatement resulted in total adjustments of only $1.2 million for 2004 and $7.9 million for 2005. *Id.* ¶¶ 133, 135. As a result, net revenue in 2004 was reduced from $144.4 million to $143.2 million (with net income reduced from $19 million to $17.9 million), and net revenue in 2005 was reduced from $184.2 million to $176.3 million (with net income reduced from $33.9 million to $26.1 million). *Id.*[5]

[5] As explained in the restatement, Connetics had been estimating its return rate based on cumulative historical return experience rather than the most recent three years' data, and it had been calculating the value of the estimated returned products based on the original sales price rather than the price following any price increases. In addition, Connetics' reserve estimates were impacted by inaccurate and inconsistent inventory level reports provided by its three main wholesale customers. Ex. 7, at 31, 43-44 (Form 10-K/A). Once Connetics began to receive accurate reports, it was able to conclude that its product inventory at these wholesalers was higher than previously estimated, and accordingly took steps to increase its reserves. *See id.*

E. Procedural History

Fifteen months after Connetics announced that the FDA had not approved Velac, several class action suits were filed. The initial suits, commenced in September 2006, were filed in this District against Connetics, Mr. Wiggans, Mr. Vontz, and a former Connetics officer represented separately by other counsel, Dr. Alex Yaroshinsky. Each suit alleged a class period that spanned over two years and brought claims related to the Velac approval process and Connetics' financial statements. In October 2006, other plaintiffs filed class action suits in the Southern District of New York. The New York suits repeated virtually verbatim the allegations in the first-filed California suits. Plaintiffs in the California suits then began to dismiss their complaints voluntarily in favor of the New York cases. While pending in New York, plaintiff here – the Teachers' Retirement System of Oklahoma – was appointed lead plaintiff.[6]

Shortly thereafter, plaintiff filed an amended complaint (adding certain parties including Mr. Higgins and Dr. Krochmal), and defendants notified plaintiff of their intent to file a motion to transfer venue from New York to this District. That motion was granted. Following transfer, plaintiff again amended its complaint. In its current form, plaintiff purports to assert claims under Sections 10(b), 20A, and 20(a) of the 1934 Act on behalf of purchasers of Connetics common stock between January 27, 2004 and July 9, 2006.

III. LEGAL STANDARDS

With the enactment of the Reform Act, Congress imposed new and more stringent pleading standards on class actions filed under the 1934 Act in order to deter "abusive securities fraud claims." *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 973 (9th Cir. 1999); *In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1084-85 (9th Cir. 2002). The Ninth Circuit has

[6] On March 26, 2006, the SEC filed an insider trading case against Dr. Yaroshinsky in the Southern District of New York. Dr. Yaroshinsky was the former Vice President of Biostatistics and Clinical Operations for Connetics. The SEC alleges that Dr. Yaroshinsky became aware of adverse facts relating to the prospects for FDA approval of Velac during the April 13, 2005 conference call with the ECAC, and he thereafter traded on inside information during a two month period ending June 13, 2005, the date that Connetics publicly disclosed the FDA non-approval letter for Velac. The SEC later amended its complaint to include Victor R. Zak, a former neighbor and alleged tipee of Dr. Yaroshinsky. While plaintiff repeatedly alleges that Connetics was under "investigation" by the SEC (AC ¶¶ 96, 126), it fails to note that the SEC has brought ***no charges whatsoever*** against it or any of its officers or directors other than Dr. Yaroshinsky.

emphasized that "[t]he Reform Act requires a plaintiff to plead a complaint for securities fraud with an unprecedented degree of specificity and detail . . . . This is not an easy standard to comply with – it was not intended to be – and plaintiff must be held to it." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003). These heightened requirements are binding on all claims in the Amended Complaint. *See* 15 U.S.C. § 78u-4(a)(1).

The Reform Act demands that plaintiffs identify precisely "each statement alleged to have been misleading, [and] the reason or reasons why [it] is misleading." 15 U.S.C. § 78u-4(b)(1)(B). Particularized facts must therefore be pled to show "the who, what, when, where, and how of the misconduct charged" for each allegedly fraudulent misstatement, on a defendant-by-defendant basis. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (quoting *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997)); *In re Silicon Storage Tech., Inc. Sec. Litig.*, No. C 05-0295 PJH, 2006 WL 648683, at *3 (N.D. Cal. Mar. 10, 2006).

Pleadings must also "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2); *Silicon Graphics*, 183 F.3d at 974; *Silicon Storage*, 2006 WL 648683, at *20 (holding that a "strong inference" must be based on "detail[s]," and plaintiffs may not "simply recite various GAAP provisions and allege in general terms that the defendants failed to comply with them"). In its recent *Tellabs* decision, the Supreme Court adopted a stringent test for pleading scienter. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509-10 (2007). To state a claim, the strong inference of scienter that arises "must be more than merely 'reasonable' or 'permissible' – it must be cogent and compelling, thus strong in light of other explanations." *Id.* at 2510. And it must be "at least as compelling" as any contrary inference: "A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

A complaint failing to meet all of these heightened requirements must be dismissed. *See* 15 U.S.C. § 78u-4(b)(3)(A). Moreover, as *Tellabs* makes plain, in assessing a complaint's sufficiency, inferences *unfavorable* to plaintiff must be considered. *See Tellabs*, 127 S. Ct. at 2510; *see also Gompper v. VISX Inc.*, 298 F.3d 893, 897 (9th Cir. 2002). In short, "[i]n few other

areas are motions to dismiss . . . so powerful" as under the Reform Act. *Ronconi v. Larkin*, 253 F.3d 423, 437 (9th Cir. 2001).

IV. PLAINTIFF'S VELAC-RELATED CLAIM FAILS AS A MATTER OF LAW

A. Plaintiff Lacks Standing To Bring A Claim Relating To Velac

Plaintiff's claim relating to Velac fails on a threshold issue: it has admitted during the lead plaintiff process that it was *not* a Connetics shareholder at the time of the Company's June 13, 2005 disclosure of the FDA's "non-approvable" letter that supposedly "revealed" the fraud. *See* Ex. 38 (Declaration of Gerald H. Silk, filed on November 17, 2006). Rather, plaintiff had sold all of its Connetics shares ***prior to*** the June 13, 2005 disclosure when, according to plaintiff, the price was still "inflated." *Id.* It then acquired more shares ***after*** the disclosure. *Id.*

Accordingly, plaintiff did not suffer any "loss" associated with Connetics' Velac-related disclosures, and therefore lacks standing to bring claims relating to such disclosures. *See Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342 (2005) (holding that a purchaser who sells before revelation of the relevant truth does not suffer any loss associated with a misrepresentation); *In re Compuware Sec. Litig.*, 386 F. Supp. 2d 913, 920 (E.D. Mich. 2005) (complaint insufficient to demonstrate economic loss where plaintiff did not own shares at time of relevant disclosure); *see also Shurkin v. Golden State Vintners, Inc.*, 471 F. Supp. 2d 998, 1022 (N.D. Cal. 2006) (plaintiff may not maintain action on behalf of a class if it does not possess the claim itself).

B. Plaintiff Has Failed To State A Claim With Respect To Forward-Looking Statements Regarding Velac

1. Connetics' Forward-Looking Statements Were Protected By The Safe Harbor

The gravaman of plaintiff's claim is that Connetics allegedly misrepresented the likelihood that Velac would be approved by the FDA between January 27, 2004 and June 13, 2005. AC ¶ 5. As such, plaintiff is necessarily challenging forward-looking statements. For example, among the putative statements are the following:

- "***Looking ahead, we are . . . preparing*** our commercial operations for the introduction of Actiza, Extina and Velac." *Id.* ¶ 60.
- "***We look forward to launching*** up to three new products from our pipeline within the next 12 months." *Id.*

- "***Velac, if approved*** . . . represents the largest sales potential of any product in our pipeline." *Id.* ¶ 48.
- "Velac gel ***will compete*** in the prescription acne market, the largest segment of the dermatology market worth more than $1.6 billion annually in the U.S., ***giving Velac Gel the potential*** to become our biggest selling product." *Id.* ¶ 41.
- "We are delighted with the strength of the Velac pivotal data . . . as Velac is a patent-protected, first-in-class combination product, ***we expect it to play an important role*** as we build a strong franchise in the $1 billion U.S. acne market . . . ***and Velac, if approved*** . . . represents the largest sales potential of any product in our pipeline." *Id.* ¶ 48.
- "***We look forward to submitting*** a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in the third quarter to seek approval to market Velac in the U.S." *Id.* ¶ 49.
- "I believe that the exceptional result that we've seen for Velac for both efficacy and safety ***may lead me to conclude*** that ***Velac will become*** the topical treatment of choice for inflammatory and noninflammatory acne." *Id.* ¶ 51.[7]

Plaintiff bears a heavy burden to plead a claim based on forward-looking statements. It must plead that the statements are not protected by the Reform Act's statutory safe harbor – *i.e.*, that they were not identified as forward-looking and accompanied by "meaningful cautionary statements." 15 U.S.C. § 78u-5(c)(1)(A)(i); *Employees Teamsters Local Nos. 175 & 505 Pension Trust Fund v. Clorox Co.*, 353 F.3d 1125, 1133 (9th Cir. 2004). Plaintiff makes no meaningful effort to do so, simply alleging the conclusion that the safe harbor "does not apply" without any analysis. AC ¶ 335. There is a good reason for this cursory approach. The challenged statements were identified as forward-looking and accompanied by the requisite cautionary language.

For instance, Connetics expressly identified the statements regarding "the market potential for Velac" and the "likelihood of approval of Velac" as forward-looking (Ex. 11 (Form 8-K)), identified a number of factors that could cause results to differ, and pointedly warned that "in particular, Connetics faces risks and uncertainties that . . . Velac may not be approved by the FDA in the timeframes projected, if at all." (Ex. 12 (Form 8-K)).[8] Connetics also repeatedly warned, with respect to Velac and other products in its pipeline, that "successful product development in

[7] *See also* AC ¶¶ 199, 202, 208, 219, 224, 238, 242, 243, 244, 257.

[8] In fact, from the very beginning, Connetics disclosed that it "faces risks and uncertainties that U.S. development of Velac may not succeed" and that "Velac may not be approved for marketing in the U.S." Ex. 8 (Form 8-K).

our industry is highly uncertain, [that] the process of obtaining FDA and other regulatory approvals is lengthy and expensive," and that as a result "very few research and development projects produce a commercial product." Ex. 3, at 18; Ex. 4, at 20; Ex. 5, at 24; Ex. 6, at 23 (Forms 10-K). Among other things, it further disclosed that "product candidates that appear promising in the early phases of development may not reach the market for a number of reasons," including "because the FDA has substantial discretion in the approval process" and "may not interpret our clinical data the way we do." *Id.* Put simply, Connetics' forward-looking statements fall squarely within the safe harbor provision.[9]

Courts have held that such statements are not actionable as a result. For example, in *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04CV-1030, 2005 WL 4161977, at *2 (D. Colo. Oct. 20, 2005), plaintiff alleged that "defendants misrepresented the strength of the . . . NDA by failing to disclose factors that might lead the FDA to reject the application." As here, plaintiff based its claim on defendants' optimistic statements regarding the likelihood of FDA approval. The court held that plaintiff's claim was barred by the safe harbor provision:

> Significantly, the plaintiff does not allege that the defendants explicitly assured investors that FDA approval would soon be obtained. . . . Projections about the likelihood of FDA approval are forward-looking statements. They are assumptions related to the Company's plan for its product, and as such fall under the PSLRA's safe harbor rule. . . . [The company's] statements are sufficient to inform a reasonable investor about the uncertainties surrounding FDA approval. Investors who purchased [the company's] stock during the Class Period had notice that a risk of investing was that the FDA might not approve RSR13 in the near term or ever.

Id. at *8-9; *see also In re Thoratec Corp. Sec. Litig.*, No. C-04-03168 RMW, 2006 WL 1305226, at *6-7 (N.D. Cal. May 11, 2006) (granting motion to dismiss where cautionary language barred claims relating to forward-looking statements); *In re Columbia Labs., Inc. Sec. Litig.*, 144 F. Supp. 2d 1362, 1368-71 (S.D. Fla. 2001) (same).

The same reasoning applies here. Because Connetics never guaranteed approval, but instead repeatedly indicated that FDA approval was uncertain, plaintiff's claim fails as a matter of law without further inquiry. *See Harris v. Ivax Corp.*, 182 F.3d 799, 803-04 (11th Cir. 1999)

[9] Exhibit 40 summarizes some of the meaningful cautionary language related to Velac gel that Connetics disclosed in its public filings and statements.

("All of the statements that the plaintiffs claim to be false or misleading are forward-looking. They were accompanied, moreover, by 'meaningful cautionary language.' Because we reach this conclusion, we need not in this case enter the thicket of the PSLRA's new pleading requirements for scienter; if a statement is accompanied by 'meaningful cautionary language,' the defendants' state of mind is irrelevant."); *In re Portal Software, Inc. Sec. Litig.*, No. C-03-5138 VRW, 2006 WL 2385250, at *12 (N.D. Cal. Aug. 17, 2006) (same).[10]

2. Even If Not Protected By The Safe Harbor, Plaintiff Has Failed To Plead Facts Showing That Each Defendant Had Actual Knowledge Of Falsity

Even if the safe harbor did not apply, plaintiff's claim would fail because it has not pleaded facts showing that each defendant had "actual knowledge" that any forward-looking statement was false when made. 15 U.S.C. § 78u-5(c)(1)(B) (requiring plaintiff to prove actual knowledge of falsity in absence of meaningful cautionary language); *Ronconi*, 253 F.2d at 429 (same). To the contrary, the most plaintiff can allege is that "senior management defendants knew ***or should have known***" that "the FDA was unlikely to approve Velac" since June 28, 2004. AC ¶ 58 (emphasis added). "Should have known" allegations are plainly insufficient, and plaintiff's need to plead that formulation itself demonstrates that its allegation of "actual knowledge" concerning an inherently uncertain future event – whether the FDA would or would not approve Velac – has no basis.

In any event, plaintiff's theory that Connetics failed to correctly predict the outcome of the FDA's review rests entirely on two allegations: (1) the adverse results in the preclinical mouse study (*id.* ¶¶ 56, 58),[11] and (2) the supposed statement of an unidentified member of the "expert

[10] Many of the statements are also not actionable because they simply reflect corporate optimism regarding a future event. *See In re Bristol-Meyers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004) (statements that "we think [the drug has] real blockbuster potential," and may be "ready to go to market hopefully next year," were not actionable because it is "well settled that a complaint alleging violations of the securities laws may not rely upon statements that are true, or constitute puffery or ordinary expressions of corporate optism"); *In re Calpine Corp. Sec. Litig.*, 288 F. Supp. 2d 1054, 1088 (N.D. Cal. 2003) (same); *see, e.g.*, AC ¶ 48 ("we expect [Velac] to play an important role as we build a strong franchise"), ¶ 202 ("[we] look forward to launching up to three new products"), ¶ 224 ("very excited that we achieved our goal" of filing NDA), ¶ 239 ("robust product pipeline"), ¶ 242 ("we are confident that we will be successful in this market with our acne franchise").

[11] Because plaintiff acknowledges that the preclinical study was not completed until late June

panel" convened by Connetics in June 2004, made to an unidentified employee of Connetics, that he or she "did not know of any drug that exhibited a 'positive dermal' similar to Velac that had ever been approved by the FDA" (*id.* ¶ 57).[12] Not only does plaintiff fail to allege when, how or by whom each defendant was supposedly made aware of this putative comment, but supposed awareness of some adverse information – even if it had been adequately alleged – does not render a forward-looking statement knowingly false. *See Ronconi*, 253 F.3d at 434 ("[P]roblems and difficulties are the daily work of business people. That they exist does not make a lie out of any of the alleged false statements"). To the contrary, adverse information arises routinely in the course of seeking approval of a new drug, and without more does not show that any speaker knew that a prediction was untenable. *See In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 930 (9th Cir. 1996); *In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 42 (2d Cir. 2000).

For example, in *Syntex*, plaintiff alleged that defendants knew of undisclosed "deficiencies in its testing procedures" for a new drug that rendered its prediction that it would receive FDA approval false and misleading. 95 F.3d at 930. The Ninth Circuit rejected this claim:

> This claim fails . . . . This was a forecast, and Plaintiffs did not plead facts showing that the statement was false when made as required under Rule 9(b). In estimating a date for FDA approval of OTC Naprosyn, Syntex was making a prediction far in advance, while the drug was still in the testing stage, about an approval decision that lies in the hands of a regulatory body. Thus, Syntex was forecasting a future event. ***Any alleged deficiencies in the testing procedures do not indicate that Syntex's prediction of an FDA approval date was false when made. Instead, the company could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval by the estimated date.*** Clearly, Defendants' prediction of a date for a regulatory decision over which they did not have control, made that far in advance, for a drug that was still in the testing stages, could not carry a guarantee of accuracy or reliability.

2004 (AC ¶¶ 55-58), plaintiff has no basis for even suggesting that Connetics' statements concerning Velac up to five months earlier were false in any way. Accordingly, the allegations in AC ¶¶ 47-49 and 51 fail.

[12] Although plaintiff provides no specifics with respect to this alleged statement by a member of the expert panel, the Amended Complaint admits that the ultimate conclusion of the expert panel was that the result of the preclinical study was due to limitations in the Tg.AC model. *See* AC ¶¶ 257, 261. In other words, plaintiff does not plead that any member of the expert panel expressed the view that Velac was unsafe or a tumor promoter. In addition, to the extent that a member of the panel allegedly stated that he or she was "unaware" of a drug with a "positive dermal" being approved, such an understanding by an unidentified panel member does not show "actual knowledge" of falsity by any defendant, particularly since benzoyl peroxide is precisely such an approved drug.

Id. (emphasis added); *see also Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 53 (2d Cir. 1995) (holding that disclosure of FDA inspection deficiencies was not required where "one cannot infer that it was a 'forgone conclusion'" that the plant would fail the inspection and the FDA would close the plant); *In re iPass, Inc. Sec. Litig.*, No. C 05-00228 MHP, 2006 WL 496046, at *7 (N.D. Cal. Feb. 28, 2006) (plaintiffs must show that defendants were aware of facts that "made [those] projections untenable").

Rather than being a "foregone conclusion" that FDA approval would not be obtained following the June 2004 Tg.AC mouse study, Connetics had reason to be optimistic, including by virtue of Velac's impressive results in Phase III clinical trials in humans (*see* AC ¶¶ 44-48); prior testing in human populations in Europe and approval in France (*see* Exs. 8, 15 (Forms 8-K)); the lack of any adverse comments by the FDA during the pre-NDA process, in the 74-day letter, or at any other time prior to April 13, 2005 (*see* AC ¶¶ 68, 261); the limitations of and number of "false positives" associated with the Tg.AC model (*see id.* ¶¶ 56, 75, 257, 261); and the fact that competitive products, such as benzoyl peroxide, had been approved notwithstanding a "positive signal" in a Tg.AC mouse study (*see* AC ¶ 257; *supra* at 7). *See Ronconi*, 253 F.3d at 434 (putative knowledge of undisclosed "serious operational problems" does not render optimistic statement misleading); *In re CBT Group PLC Sec. Litig.*, No. C-98-21014 RMW, 1999 WL 1249287, at *3 (N.D. Cal. July 20, 1999) (even "if a company knows that a problem exists, it could still honestly and in good faith report that the company will continue to perform as expected").[13]

Moreover, courts have held that a defendant cannot be held liable for securities fraud based on optimistic projections of FDA approval ***even where (unknown to investors) the FDA itself has raised concerns*** about the approvability of the drug. *See Noble Asset Mgmt.*, 2005 WL 4161977 at *7 (holding that "[t]he fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report

[13] As indicated above, even the ECAC's comments on April 13, 2005 did not render approval a foregone conclusion since, by their express terms, the ECAC's statements "should not be interpreted" by Connetics "as a measure of the approvability of their application." Ex. 29 (FDA Manual § 7412.2).

to the public the substance of their conversations with the FDA"); *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) (same); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1224 (S.D. Cal. 2001) (holding that undisclosed statements made by FDA advisory committee about the toxicity problems of product did not foreclose the possibility of FDA approval). Here, the FDA made ***no*** negative statements about Connetics' preclinical study result at any time prior to April 13, 2005, which was then promptly disclosed. *See In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d 153, 157 (2d Cir. 1998) (no need to disclose that new drug may have caused deaths until company had "statistically significant" scientific evidence demonstrating that the "commercial viability of [the drug] was threatened").[14]

In any event, plaintiff's claim of "actual knowledge" is irreconcilable with the concrete business decisions Connetics made following the preclinical study. Among other things, Connetics paid $3.5 million as a milestone payment to Yamanouchi upon filing the NDA in August 2004 (AC ¶¶ 217, 222); it devoted resources to the time consuming and expensive process of seeking FDA approval (*id.* ¶¶ 47-49); it hired and trained dozens of sales people (*id.* ¶ 242); and it prepared for commercial operations to manufacture, distribute and sell Velac if and when it was approved (*id.* ¶¶ 202, 242, 244). *See In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1118 (9th Cir. 1989) (scienter dispelled by decision to pour "millions of dollars into product development, market research and promotions"); *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1420 (9th Cir. 1994) (same).

As the Ninth Circuit observed in *Ronconi*, it is a fundamental reality that "business decisions have to be based on predictions about the future . . . ." 253 F.3d at 428. Here, the business decisions Connetics made would simply make no sense if defendants "knew" all along that Velac would not be approved. *See id.* at 437 ("[c]alling executives bad managers, or bad

[14] Still other courts have dismissed securities fraud claims based on a defendant's alleged failure to disclose adverse test results relating to a new drug where (as here) reasonable minds could differ on the significance of the results. *See DeMarco*, 149 F. Supp. 2d at 1225 ("Although Plaintiffs may have established a legitimate difference in opinion as to the proper statistical analysis, they have hardly stated a securities fraud claim."); *Padnes v. Scios Nova Inc.*, No. C 95-1693 MHP, 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996) ("The fact that plaintiffs disagree with the Colorado researchers and with defendants about the import of the Colorado data does not make defendants' summaries of the study false or misleading. The court finds that defendants' statements were within the realm of permissible judgment.").

forecasters, does not plead fraud"). Indeed, under *Tellabs*, no "cogent and compelling" inference of scienter possibly emerges from the pleaded facts. 127 S. Ct. at 2509-10; *see also Acito*, 47 F.3d at 53 (defendants' "lack of clairvoyance simply does not constitute securities fraud"); *Noble Asset Mgmt.*, 2005 WL 4161977, at *11 ("The fact that the ODAC ultimately did not recommend approval does not mean that the defendants' statements about the results or design of the study were false. The plaintiff's characterization of the defendants' statements as misleading falls into the category of 'fraud by hindsight.'").

C. Plaintiff Has Failed To Allege Any Other Misstatement Or Scienter Concerning Velac

Although hardly a model of clarity, the Amended Complaint nonetheless appears to allege that ***any*** statement ever made by Connetics about Velac during the class period – regardless of the subject matter – was false and misleading because of the "omission" of any reference to the preclinical study.[15] Thus, plaintiff challenges statements that Connetics was "working diligently to finalize its NDA submission" (AC ¶ 208), that it had actually "filed" its NDA (*id.* ¶¶ 219, 234, 236), that it had paid Yamanouchi $3.5 million upon filing the NDA (*id.* ¶¶ 217, 222), that clinical results in Phase III were outstanding (*id.* ¶ 199, 255), that it will owe Yamanouchi an additional $5 million if the FDA approves Velac (*id.* ¶ 238), and that Connetics had expanded its sales force in anticipation of a mid-year 2005 launch for Velac (*id.* ¶ 242).

Because none of these undeniably truthful statements had anything to do with the preclinical study, plaintiff's Section 10(b) claim necessarily fails. *See, e.g., Seinfeld v. Bartz*, 322 F.3d 693, 698 (9th Cir. 2003) (statement not misleading for failure to disclose tax consequences of option grants where no statement was made pertaining to that issue); *In re Alkermes Sec. Litig.*, No. Civ. A. 03-12091-RCL, 2005 WL 2848341, at *16 (D. Mass. Oct. 6, 2005) ("when revealing

[15] In this respect, plaintiff employs improper "puzzle-pleading" by simply regurgitating large blocks of quotes from Connetics' public statements in the class period concerning a host of subjects, and then alleging in a single conclusory sentence that they are misleading in an unspecified way for the putative reason vaguely referenced elsewhere in the Amended Complaint. *See, e.g.*, AC ¶¶ 178-332. This form of pleading violates the Reform Act, which requires plaintiff to specify the reasons why *each* statement is misleading (15 U.S.C. § 78u-4(b)(1)(B)), and by itself justifies dismissal. *See Shuster v. Symmetricom, Inc.*, No. C 94-20024 RMW (PVT), 1997 WL 820967, at *1 (N.D. Cal. June 25, 1997); *Wenger v. Lumisys, Inc.*, 2 F. Supp. 2d 1231, 1243-44 (N.D. Cal. 1998).

facts such as a submission of an NDA, a company need not reveal all others that, too, would be interesting," but must only disclose those that would render an affirmative statement misleading). In this respect, plaintiff does not even try to identify, with the required specificity, how or what in these statements was supposedly rendered false, notwithstanding the requirements of the Reform Act. 15 U.S.C. § 78u-4(b)(2)(B); *Vess*, 317 F.3d at 1106. [16]

In fact, plaintiff's allegation appears to be based on the notion that Connetics had an independent obligation to publicly disclose the results of its preclinical mouse study. It is axiomatic, however, that liability for failure to disclose must be predicated on a legal duty to do so. *See Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988). There is simply no duty to disclose preclinical study results, or communications with the FDA about such results. *See Syntex*, 95 F.3d at 930 (no duty to disclose testing deficiencies identified by FDA); *Acito*, 47 F.3d at 53 (no duty to disclose plant deficiencies identified by FDA); *Alkermes*, 2005 WL 2848341, at *16 (no duty to disclose FDA request for further studies); *In re Boston Scientific Corp. Sec. Litig.*, 490 F. Supp. 2d 142, 161 (D. Mass. 2007) (no duty to disclose FDA warning letter); *MedImmune*, 873 F. Supp. at 968 (no duty to disclose FDA questions regarding drug under review).[17]

Nor has plaintiff pleaded facts to show that Connetics' April 26, 2005 disclosures

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[16] The allegation fails for further reasons as well. For example, plaintiff's complaint that Connetics did not disclose the ECAC's alleged comment that the preclinical result was a "serious issue" is not only belied by the fact that Connetics filed a Form 8-K regarding the comment (which concerns material developments, *i.e.*, serious issues), but it ignores the fact that, according to the ECAC itself, its comments are *not* to be interpreted as a measure of approvability. *See, e.g.*, Ex. 17 (Form 8-K disclosing ECAC's comment under "Item 8.01"); Ex. 23, at 20 (instructions for filing Form 8-K) (issuer may disclose events under Item 8.01 on Form 8-K that it "deems of importance to security holders"); 15 U.S.C. § 78m(l) (requiring issuers to disclose "material changes" in operations on current report). Similarly, plaintiff's repetition of the allegation concerning the statement of the unidentified member of the expert panel (that he or she was "unaware" of any drug that had been approved with a positive signal in a Tg.AC study) can hardly support a disclosure claim since it was public information that such a drug *had* been approved, just as Connetics disclosed.

[17] This case is unlike *In re CV Therapeutics, Inc. Sec. Lit.*, No. C 03-03709 SI, 2004 U.S. Dist. LEXIS 17419 (N.D. Cal. Aug. 5, 2004). There, the defendants disclosed that the FDA scheduled a new drug for review by its Advisory Committee and the issuance of an FDA approvability letter, but misled investors by failing to disclose the additional facts that the FDA believed such a Committee meeting was unlikely and that the FDA found major deficiencies pertaining to the defendants' clinical studies. In contrast, Connetics never publicly discussed preclinical test results or discussions with the FDA. As such, there can be no claim based on those results or discussions. *See id.* at *27 (noting plaintiff's argument that "once defendants started to reveal the contents of conversations with the FDA, they had the duty to be truthful").

concerning its recent communications with the FDA's advisory committee (the ECAC) regarding the preclinical study were materially misleading, much less that they were made with the intent to deceive. *See Tellabs*, 127 S. Ct. at 2510; *Silicon Graphics*, 183 F.3d at 974. These disclosures, made on Form 8-K and in a conference call, indicated that (1) the preclinical study for carcinogenicity resulted in a "positive response," (2) Connetics and the FDA disagreed over the interpretation of the data, (3) Connetics had been advised by a panel of experts that the positive response was the result of the limitations in the Tg.AC model; (4) other products had been approved notwithstanding a similar result in the Tg.AC model, (5) the FDA had not raised this issue previously, and (6) discussions with the FDA were ongoing. *See* AC ¶¶ 257, 261; Ex. 17 (Form 8-K); Ex. 1, at 5-6 (analyst call transcript). According to plaintiff, Connetics' share price declined from over $27 to $22.30 after this announcement. AC ¶ 333(i).

Plaintiff wrongly contends that these disclosures were misleading because they did not convey further details concerning what the FDA allegedly said (*see id.* ¶¶ 76-77), or that the preclinical study was done nearly a year earlier, the significance of which is never explained (*see id.* ¶ 76). The law is clear that more details are not required where (as here) Connetics had fairly summarized the communication and the risks were abundantly apparent, as evidenced by plaintiff's own allegation regarding the decline in Connetics' stock price, and the reaction of analysts who revised their estimates about Connetics. *See Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002) (Rule 10b-5 does not contain "a freestanding completeness requirement" mandating disclosure of all details); *Anderson v. Abbott Labs.*, 140 F. Supp. 2d 894, 900 (N.D. Ill.), *aff'd*, 269 F. 3d 806 (7th Cir. 2001) (rejecting disclosure claim where "Abbott was still negotiating with the FDA, and the FDA had not yet filed suit" and "Abbott expressed its opinion about its own compliance, but the risks were abundantly apparent on the statement's face"); *City Capital Assocs. Ltd. P'ship v. Interco, Inc.*, 696 F. Supp. 1551, 1556-57 (D. Del.), *aff'd*, 860 F.2d 60 (3d Cir. 1988) ("Where there exists a good faith dispute as to facts or an alleged legal violation, the [law] only requires disclosure of the dispute"); *see also In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 268 (2d Cir. 1993) (rejecting argument that "whenever a corporation speaks, it must disclose every piece of information in its possession" on the topic).

Connetics was not required to predict that the FDA would not approve Velac, or change its own opinion that approval could be obtained. "The fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the FDA." *Noble Asset Mgmt.*, 2005 WL 4161977 at *7. Put simply, whatever hindsight plaintiff now offers, the proposition that Connetics would voluntarily make the April 26, 2005 disclosure, yet deliberately tell a half-truth at the time, is unsupported by contemporaneous facts showing that defendants did not believe the disclosures were reasonable and accurate. *See Shuster v. Symmetricom*, No. C9420024RMW, 2000 WL 33115909, at *7 (N.D. Cal. Aug. 1, 2000) ("courts do not presume that corporate officers make false statements simply out of spite or to impress others").[18]

D. Plaintiff's Miscellaneous Other Theories Of Scienter Are Deficient

1. Plaintiff's Insider Trading Allegations Actually Eviscerate Scienter

There is nothing improper about an officer selling stock. *Vantive*, 283 F.3d at 1092. Only allegations of "unusual" or "suspicious" insider trading during a class period can support a strong inference of scienter. *Ronconi*, 253 F.3d at 435. "[I]nsider trading is suspicious only when it is 'dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information.'" *Silicon Graphics*, 183 F.3d at 986, quoting *Apple*, 886 F.2d at 1117; *see also Ronconi*, 253 F.3d at 435. Here, the facts contained in the Amended Complaint actually ***refute*** any inference of scienter (as to both Velac and the alleged financial statement issues), rather than provide the "cogent and compelling" inference needed to plead a claim. *See Tellabs*, 127 S. Ct. at 2509-10.

By way of example, Dr. Krochmal – Connetics' EVP of Research & Product

[18] Plaintiff also resorts to blanket inferences based on the positions of defendants, their membership on the company's executive committee, and the importance of Velac to the company. *See, e,g.*, AC ¶¶ 147-48, 151-54. Such allegations are not enough to plead scienter. *See Vantive*, 283 F.3d at 1087-88 (defendants' knowledge not adequately established by allegations of "hands-on" management style or "attendance at meetings"); *In re Autodesk, Inc. Sec. Litig.*, 132 F. Supp. 2d 833, 844 (N.D. Cal. 2000) (complaint inadequate where plaintiff alleged that officers had knowledge "by virtue of their 'hands-on' positions"); *In re Read-Rite Corp. Sec. Litig.*, 115 F. Supp. 2d 1181, 1183 (N.D. Cal. 2000), *aff'd*, 335 F.3d 843 (9th Cir. 2003) (allegations that defendants' knowledge rests on assumption that persons with defendants' job titles and duties should have known of facts in question insufficient to plead scienter).

Development – is ***not alleged to have sold any shares whatsoever in the class period***. The utter absence of such sales by an officer who, according to plaintiff, was otherwise heavily involved in the efforts to obtain approval of Velac eviscerate the notion that defendants acted with scienter. *See In re Glenayre Techs. Inc. Sec. Litig.*, No. 96 CIV 8252, 1998 WL 915907, at *4 (S.D.N.Y. Dec. 30, 1998), *aff'd*, 201 F.3d 431 (2d Cir. 1999) ("one can assume that these high-ranking corporate officers, arguably the most knowledgeable . . ., would be part of any fraudulent scheme to benefit from insider information through pre-emptive stock sales"); *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 540 (3d Cir. 1999) (no scienter where some defendants did not sell stock); *In re First Union Corp. Sec. Litig.*, 128 F. Supp. 2d 871, 899 (W.D.N.C. 2001) (lack of trading refutes scienter).

Moreover, the amount of shares sold by other defendants is hardly suspicious or indicative of a scheme to defraud, since each retained the vast majority of his shares. Each defendant's total class period sales, along with the percentage of holdings sold, is set forth below:

Defendant	Class Period Stock Sales	Percent of Holdings Sold[19]
John Higgins	130,517	17.8%
Lincoln Krochmal	None	0%
Gregory Vontz	32,279	4.2%
Thomas G. Wiggans	190,380	11.1%
Aggregate Total	353,176	10.3%

See Ex. 39 (summarizing defendants' stock sales and holdings).

There is nothing "inherently alarming or unusual" about an insider selling "a quarter of his

[19] This percentage calculates the total stock sold as a percentage of defendants' ownership of common stock and "exercisable" stock options as of May 23, 2006, nearly three months after the last transaction challenged by plaintiff. *See* AC ¶ 165; Ex. 27, at 9 (proxy statement); Ex. 39 (summary of defendants' sales and holdings). The calculation includes common stock as well as exercisable options because "[a]ctual stock shares plus exercisable stock options represent the owner's trading potential more accurately than the stock shares alone." *Silicon Graphics*, 183 F.3d at 986-87; *see Ronconi*, 253 F.3d at 435-36. Although the Amended Complaint lists Mr. Wiggans' class period sales, those sales actually total 190,380 shares. Plaintiff's "total" adds the numbers incorrectly as 207,280. *See* AC ¶ 165. Likewise, plaintiff erroneously states that Mr. Vontz made two trades on May 10, 2004. *Id.* ¶ 165. As his amended Form 4 filed shortly thereafter indicates, Mr. Vontz made only one trade of 10,000 shares at that time. AC ¶ 165; Ex. 26 (C.G. Vontz, May 11, 2004 Form 4; C.G. Vontz, May 19, 2004 Form 4/A).

holdings over the course of fifteen months, particularly in a volatile industry." *Vantive*, 283 F.3d at 1094. Dr. Krochmal, Mr. Vontz, Mr. Wiggans, and Mr. Higgins sold only 0%, 4.2%, 11.1%, and 17.8% of their respective holdings during the two and one-half year class period – well below amounts the Ninth Circuit has held are not exceptional. *See id.*; *Ronconi*, 253 F.3d at 435; *Silicon Graphics*, 183 F.3d at 987. As defendants "held onto most of their . . . stock and incurred the same large losses" as shareholders, the Amended Complaint cannot plead a strong inference of scienter. *Worlds of Wonder*, 35 F.3d at 1424-25.[20]

Moreover, defendants' class period sales were not "dramatically out of line with prior trading practices or otherwise suspicious enough to create a strong inference of the required deliberate recklessness." *Silicon Graphics*, 183 F.3d at 987; *see also Vantive*, 283 F.3d at 1095 (sale of 61,000 shares during 15-month class period not "dramatically out of line" with sale of 10,000 shares during preceding nine months). In fact, Mr. Vontz sold 54,910 shares during the 30 months prior to the class period, or 170% *more* shares than he sold during the 30-month class period. *See* AC ¶¶ 165-66; Ex. 39 (stock sales chart). Likewise, Mr. Wiggans and Mr. Higgins sold substantially the same amount of shares (142,563 shares and 95,399 shares respectively) in the preceding 30-month period as they did during the class period (*id.*), thus negating the notion that their sales were somehow "dramatically out of line with prior trading." *Silicon Graphics*, 183 F.3d at 987; *see also Vantive*, 283 F.3d at 1095.

2. Plaintiff's Generic Allegations Of Other Motives Are Insufficient

Plaintiff also wrongly alleges that defendants engaged in fraud to complete a debt financing and receive an undefined benefit through a share repurchase program. *See* AC ¶¶ 158-59. Such generalized allegations of motives have been repeatedly rejected as insufficient to show scienter. *Lipton v. PathoGenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002) (alleged desire to obtain favorable financing is a normal corporate objective insufficient to allege scienter);

[20] Furthermore, as is evident from the face of defendants' Form 4s, most of their sales were made pursuant to ***pre-arranged written stock trading plans***. *See* Exs. 24-26 (Forms 4) ("Sale pursuant to plan adopted under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended."); 17 C.F.R. § 240.10b5-1 (describing plans). Rather than raise a strong inference of scienter, the use of these plans "raise an inference that the sales were pre-scheduled and not suspicious." *Wietschner v. Monterey Pasta Co.*, 294 F. Supp. 2d 1102, 1117 (N.D. Cal. 2003).

Marksman Partners L.P. v. Chantal Pharm. Corp., 927 F. Supp. 1297, 1310-12 (C.D. Cal. 1996) (motive to raise money in private placement insufficient); *Meyer v. Biopure*, 221 F. Supp. 2d 195, 209 (D. Mass. 2002) (same). Plaintiff also claims that defendants were motivated by a desire to enhance their respective compensation packages. *See* AC ¶¶ 168-77. But this too "is a generic motive that could apply to any decision maker accused of participating in a securities fraud" and therefore is not enough to plead a strong inference of scienter. *In re Carter-Wallace, Inc. Sec. Litig.*, No. 94 CIV. 5704(KTD), 1999 WL 1029713, at *4 (S.D.N.Y. Nov. 10, 1999), *aff'd*, 220 F.3d 36 (2d Cir. 2000).

E. Plaintiff Has Failed To Allege Loss Causation As To The Challenged Velac Statements

Loss causation is an essential element of a Section 10(b) claim. The only investment loss that is recoverable is one that was caused by disclosure of the alleged fraud. *Dura*, 544 U.S. at 342-43; 15 U.S.C. § 78u-4(b)(4). The relevant facts must "become generally known" and "as a result share value depreciates." *Dura*, 544 U.S. at 344 (quotation omitted); *see In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1025 (9th Cir. 2005), *cert. denied*, 126 S. Ct. 1335 (2006). As set forth above, plaintiff was not a Connetics shareholder on June 13, 2005, when the FDA's non-approvable letter was disclosed, and hence did not suffer any loss when Connetics' stock price declined. Accordingly, it cannot show loss causation associated with the so-called "fraud" revealed at that time. *See, e.g.*, *Dura*, 544 U.S. at 342 (person who sells before disclosure of the relevant truth has no claim).

Apparently recognizing this, plaintiff attempts to allege that the truth was "partially revealed" on April 26, 2005 when plaintiff still owned some Connetics shares. AC ¶¶ 333, 74-77. But the April 26 disclosure did not "reveal" any putative fraud; rather, among other things, it merely summarized recent communications with the FDA. *See id.* ¶¶ 257, 261. Although that disclosure may have been interpreted as bad news and that a publicly disclosed risk might be realized – namely, that the FDA may not approve Velac – plaintiff must show that the loss was caused by "the materialization of the ***concealed*** risk." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir.), *cert. denied*, 126 S. Ct. 421 (2005) (emphasis added). Since Connetics

repeatedly disclosed that approval of Velac was uncertain, plaintiff cannot do so.[21]

Finally, because plaintiff has failed to allege specific facts demonstrating that the April 26, 2005 disclosure is actionable, it cannot show as a matter of law that the alleged misconduct caused its losses. *See In re Cyberonics Inc. Sec. Litig.*, No. H-05-2121, 2006 WL 2050696, at *11 (S.D. Tex. July 20, 2006) ("Absent some actionable conduct by Defendants, the Court cannot find that Plaintiffs have alleged proximate causation and is left only with the inference that the losses were caused by other factors, *i.e.*, the FDA's non-approvable letter and ANSI's decision to drop its merger bid after Cyberonics expressed its disinterest.").

V. PLAINTIFF'S CLAIM PERTAINING TO CONNETICS' FINANCIAL STATEMENTS AND RESULTS FAILS AS A MATTER OF LAW

A. Plaintiff Has Failed To Plead Facts Showing That Connetics Deliberately Misstated Its Financials Or Results

In the wake of Connetics' voluntary restatement of its 2004 and 2005 financial statements, plaintiff asserts the all too predictable claim of "fraud." *See* AC ¶¶ 10, 100. Although plaintiff offers plenty of rhetoric – asserting that Connetics perpetrated a "massive financial fraud" in an effort to "deliberately deceive" investors (*id.* ¶ 10) – it never identifies concrete facts to back up those conclusions. That is hardly surprising given that plaintiff's accusations are not only inconsistent with the modest size of the restatement – which resulted in a total of just $1.1 million in adjustments in 2004 and $7.9 million in 2005 – but are unsupported by contemporaneous facts showing that the restatement was the product of fraud rather than an innocent misjudgment or even negligent error. *See, e.g.*, *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 390 (9th Cir. 2002) (the mere fact of a restatement is not enough because "publication of inaccurate accounting figures, or a failure to follow GAAP, without more, does not establish

[21] In any event, where, as here, plaintiff claims that defendants continued to "conceal" facts after a disclosure, courts have held that the "relevant truth" – that a defendant engaged in wrongdoing rather than merely disclosing negative news based on recent developments – is not present at the time of the disclosure and loss causation has not been pleaded. *See, e.g.*, *Powell v. Idacorp, Inc.*, No. Civ. 04-249-3-EJL, 2007 WL 1498881, at *5 (D. Idaho May 21, 2007) ("Even if the forecast reductions were 'partial revelations' of the 'impact' of the Defendants' misconduct on the company, the Court finds that loss causation has not been pled because the amended complaint still alleges that the Defendants continued to conceal the misconduct and, therefore, any market reaction was not caused by knowledge of the improper activity.").

scienter"); *In re Ramp Networks, Inc. Sec. Litig.*, 201 F. Supp. 2d 1051, 1066 (N.D. Cal. 2002) ("Because the restatements were not explicit admissions of falsity by Defendants, [they] do not by themselves satisfy the requirement that Plaintiffs plead specific facts showing the statements at issue were false when made.").

There is no disagreement that Connetics determined that certain of its reserves needed to be restated because they had not adequately captured the potential for returns, rebates or chargebacks. As courts have repeatedly recognized, however, reserves are simply estimates of future events and involve a high degree of subjective judgment, based on "flexible accounting principles." *Kane v. Madge Networks N.V.*, No. C-96-20652-RMW, 2000 WL 33208116, at *5-6 (N.D. Cal. May 26, 2000), *aff'd sub nom.*, 3 Fed. Appx. 905 (9th Cir. 2002); *see also Mathews v. Centex Telemanagement, Inc.*, No. C-92-1837 CAL, 1994 WL 269734, at *6 (N.D. Cal. June 8, 1994) (reserves are estimates, and plaintiff must show they were deliberately "derived in a manner inconsistent with reasonable accounting practices") (quotation omitted). Thus, alleging that reserves should have been higher does not support a claim for securities fraud; rather, plaintiff must plead particularized, contemporaneous facts showing that defendants knowingly or deliberately set reserves at insufficient levels at the time. *Kane*, 2000 WL 332028116, at *5-6; *Vantive*, 283 F.3d at 1090-91 (plaintiff must "allege specific contemporaneous conditions known to the defendants that would strongly suggest that the defendants understood" that their accounting was improper at the time).

Plaintiff has not even tried to plead such facts. The Amended Complaint does not allege – quarter by quarter, year by year, or otherwise – what Connetics' reserves in each period were, who set them, what contemporaneous information existed establishing that the reserves in each period were inadequate and deliberately set too low, or who had such information. Nor does the Amended Complaint link such "information" to each defendant, or explain how they were involved in or knew that the reserves were insufficient. *See In re Read-Rite Corp. Sec. Litig.*, 335 F.3d 843, 846-49 (9th Cir. 2003) (scienter must be pleaded defendant by defendant). To the contrary, plaintiff provides no facts to show that Mr. Wiggans (CEO), Mr. Vontz (COO), or Dr. Krochmal (EVP of Research & Product Development) had knowledge of accounting or the level

of these reserves, and merely alleging that Mr. Higgins (who is not an accountant) was CFO is plainly insufficient. *See Morgan v. AXT, Inc.*, No. C 04-4362 MJJ, 2005 WL 2347125, at *14 (N.D. Cal. Sept. 23, 2005) (plaintiff must allege that "defendants knew specific facts that rendered their accounting determinations fraudulent").[22]

Because plaintiff lacks facts that could conceivably give rise to a strong inference of scienter on the part of each defendant, plaintiff tries to avoid the issue by generally suggesting that reserves were set inadequately to permit Connetics to meet earnings estimates. *See* AC ¶¶ 162-63. However, plaintiff does not plead any facts suggesting that anyone at Connetics manipulated or changed reserves in each of the eight quarters subject to the restatement to achieve this result, when or how they did this, or at whose direction. Instead, plaintiff simply points to math – alleging that the effect of the restatement in a few quarters (but not all) was to lower earnings below alleged guidance. *See id.* ¶ 163. But plaintiff's "math theory" ignores (1) that in three quarters, Connetics exceeded guidance even ***after*** the restatement (Q1 and Q2 of 2004, and Q3 of 2005); (2) that in one quarter, Connetics did not meet guidance even ***before*** the restatement (Q4 of 2005); and (3) that in two other quarters (Q2 of 2004 and Q2 of 2005), the effect of the restatement was to ***increase***, not decrease, Connetics' net revenue (that is, Connetics' reported net revenue was ***lower*** than it should have been).[23] In short, there is no pattern to plaintiff's "math," much less one that gives rise to the "cogent and compelling" strong inference of scienter needed to plead securities fraud. *Tellabs*, 127 S. Ct. at 2510; *see Gompper*, 298 F.3d at 897.[24]

B. Plaintiff's "Channel Stuffing" Allegations Are Insufficient To Plead Falsity Or Scienter

Because there are no facts that support a securities fraud claim with respect to Connetics'

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[22] The claim against Dr. Krochmal is particularly specious, since plaintiff does not allege that he had any responsibility whatsoever concerning Connetics' financial statements or results.

[23] *Compare* Ex. 7, at F11-15 (Form 10-K/A) *with* Ex. 10 (Jan. 27, 2004 Form 8-K) (guidance for Q1 of 2004); Ex. 12 (May 4, 2004 Form 8-K) (guidance for Q2 of 2004); AC ¶ 203 (guidance for Q3 of 2004); *id.* ¶ 223 (guidance for Q4 of 2004); Ex. 16 (Jan. 25, 2005 Form 8-K) (guidance for Q1 of 2005); AC ¶¶ 258, 262 (guidance for Q2 of 2005); Ex. 19 (Aug. 2, 2005 Form 8-K) (guidance for Q3 of 2005); AC ¶ 295 (guidance for Q4 of 2005).

[24] As set forth above in Section IV.D, plaintiff also has failed to plead scienter based on insider trading or other generic theories.

reserves that led to the restatement, plaintiff switches gears and makes the familiar allegation that Connetics "stuffed" the channel with its products. *See* AC ¶¶ 109-20. This claim is equally deficient.

The Ninth Circuit has held that "[c]hannel stuffing is the oversupply of distributors in one quarter to artificially inflate sales, which will then drop in the next quarter as the distributors no longer make orders while they deplete their excess supply." *Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1298 (9th Cir. 1998). "[L]ogically it must be a ***short-lived*** scheme in which the wrongdoer attempts to capitalize on artificially increased sales ***before*** the resulting drop in sales." *In re ICN Pharms., Inc. Sec. Litig.*, 299 F. Supp. 2d 1055, 1062 (C.D. Cal. 2004) (emphasis added).

Plaintiff must allege "channel stuffing" with particularity by describing specific instances when Connetics shipped excess product, the customer who received the product, the date of the transaction, the amount of excess product allegedly held by the customer, the amount of product that was returned, the amount improperly booked as a sale, and the basis for defendants' supposed knowledge. *See ICN*, 299 F. Supp. 2d at 1062 (dismissing channel stuffing claim where the plaintiff failed "to allege specific transactions, specific shipments, specific customers, specific times, or specific dollar amounts") (citation omitted); *In re Ashworth, Inc. Sec. Litig.*, No. 99CV0121-L(JAH), 2000 WL 33176041, at *6 (S.D. Cal. July 18, 2000) (dismissing claim where complaint failed "to identify specific instances where [defendant] shipped product to a specified customer in a specified amount and booked that sale only to have that material returned at a later date"); *In re Foundry Networks, Inc. Sec. Litig.*, No. C 00-4823 MMC, 2003 WL 22077729, at *6 (N.D. Cal. Aug. 29, 2003) (general allegations that defendants had "directed the sales and shipping departments to go ahead and ship product in September that customers had indicated should not . . . be shipped until the fourth quarter" insufficient to state channel stuffing claim) (internal quotation omitted); *see also Greebel v. FTP Software, Inc.*, 194 F.3d 185, 204 (1st Cir. 1999) (dismissing claim that failed to allege "such basic details as the approximate amount by which revenues and earnings were overstated; . . . the dates of any of the transactions; or the identities of any of the customers or . . . employees involved in the transactions") (citations

omitted).[25]

Plaintiff does not come close to meeting these controlling standards. The Amended Complaint does not identify any channel stuffing transactions. It does not identify the date of any transaction, the product involved, the customer, what Connetics did to induce the customer to accept the shipment, or how much of the product was returned (if any) or improperly booked as a sale. Nor does plaintiff allege that any channel stuffing was "short-lived," but instead makes the "illogical" suggestion that Connetics somehow induced customers to take excess product for the entire two and one-half year class period. *See ICN*, 299 F. Supp. 2d at 1067. At bottom, plaintiff's claim is nothing more than generalized allegations of improper shipments to meet quarter goals. Such a claim falls far short of the requirements for pleading securities fraud. *See Steckman*, 143 F.3d at 1298 ("This claim [channel stuffing] is speculation made in hindsight."); *Greebel*, 194 F.3d at 202 ("[t]here is nothing inherently improper in pressing for sales to be made earlier than in the normal course"); *see also Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1261 (11th Cir. 2006) ("Channel stuffing is not fraudulent *per se*").

Moreover, even assuming plaintiff had adequately alleged channel stuffing, it has failed to allege facts establishing that each defendant was aware that excess product was being sold and deliberately disregarded such information or otherwise acted with scienter. *See Tellabs*, 127 S. Ct. at 2510. For example, plaintiff does not allege that defendants engaged in particular sales practices designed to induce Connetics' customers to accept more products then they could sell through retail channels. Yet, to state a claim for channel stuffing, plaintiff must allege that defendants "coerced its customers to accept more [product] than they wanted . . . ." *In re Sierra Wireless, Inc. Sec. Lit.*, 482 F. Supp. 2d 365, 376 (S.D.N.Y. 2007); *see also In re Spectrum Brands, Inc. Sec. Lit.*, 461 F. Supp. 2d 1297, 1319 (N.D. Ga. 2006) (holding that plaintiff must

[25] *See also In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1076 (N.D. Cal. 2001) (dismissing complaint with prejudice for failing to plead channel stuffing with sufficient particularity); *Hockey v. Medhekar*, 30 F. Supp. 2d 1209, 1216 (N.D. Cal. 1998) (holding that "plaintiffs must identify the particular transactions underlying [the] alleged accounting deficiencies") (citation omitted); *In re DDi Corp. Sec. Litig.*, No. CV 03-7063 NM (SJHx), 2005 U.S. Dist. LEXIS 1056, at *64 (C.D. Cal. Jan. 7, 2005) (holding that "[plaintiff's allegations] fail to describe any particular transactions, precisely state when certain channel stuffing occurred, or, most importantly, indicate how much the channel stuffing skewed [defendant's] total results").

identify "specific transactions in which special returns, credit terms, or other incentives were authorized by the individual defendants . . . in furtherance of a fraudulent channel stuffing scheme"). Here, plaintiff's channel stuffing claim is based on the illogical premise that Connetics' customers would continually purchase product – for over two years – that they knew they could not sell without any special incentive to do so.[26]

Nor can plaintiff rely on vague allegations concerning "internal reports" to establish scienter. *See* AC ¶¶ 112-13. Plaintiff does not identify the date or contents of a single report containing historical prescription rates for any of Connetics' product; the date and content of sales forecasts; the amount by which particular sales forecasts allegedly exceeded the historical prescription data for each product; the amount of each product that was allegedly improperly shipped in reliance on each sales forecast; who prepared each report; or who had access to each report. This is exactly the type of allegation that has been repeatedly rejected as insufficient. *Lipton*, 284 F.3d at 1036 (affirming dismissal where plaintiffs did not plead "in detail, the contents of any such report or the purported data" regarding prescription rates and thus failed to establish basis for allegations that officers had knowledge of flat patient demand "that would cause their optimistic representations to the contrary to be consciously misleading") (internal quotation omitted); *In re Dreamworks Animation SKG, Inc., Sec. Litig.*, No. CV 05-03966 MRP, 2006 U.S. Dist. LEXIS 24456, at *15 (C.D. Cal. Apr. 12, 2006) (same); *Splash*, 160 F. Supp. 2d at 1070 (allegations concerning defendants' awareness of adverse information through internal reports were not supported by specific facts concerning such reports).

[26] In fact, the Complaint alleges that "[w]hen a distributor or pharmacy returned a product, Connetics would provide the customer with a credit in the amount of ninety-five percent of the then-current wholesale price of the product." AC ¶ 106. To succeed at channel stuffing as alleged by plaintiff, defendants would have to convince a customer to purchase more product than it could sell, even though the customer could potentially lose five percent of the purchase price of the product when returned. In any event, even if plaintiff alleged that defendants granted broad rights of returns, such "broad rights of return, in and of themselves, [do not] create an inference of scienter." *Ramp*, 201 F. Supp. 2d at 1077; *see also id.* at 1078 ("Nor have Plaintiffs presented any authority in support of the proposition that payment of storage fees supports an inference of scienter.").

C. Plaintiff Cannot Rely On Vague Statements Of Anonymous Witnesses To Plead Falsity Or Scienter

Plaintiff fares no better with respect to its putative reliance on "confidential witnesses" to support its claims. AC ¶¶ 111-17. As a threshold matter, in the wake of the Supreme Court's decision in *Tellabs* last month, at least one court has held that allegations based on "confidential witnesses" are improper and do not comport with the Reform Act. *Higginbotham v. Baxter Int'l, Inc.*, No. 06-1312, 2007 WL 2142298 (7th Cir. July 27, 2007). Emphasizing that the Supreme Court requires plaintiffs to plead a strong inference of scienter that is both cogent and at least as compelling as any opposing inference that can be drawn from the alleged facts, the court found that "anonymity frustrates that process." *Id.* at *2. In particular, the failure to name sources "conceals information that is essential to the sort of comparative evaluation required by *Tellabs*," because the court is unable to fully evaluate the reliability of the so-called witness. *Id.* Accordingly, allegations from confidential witnesses must be "discounted" in determining whether a plaintiff has pleaded a strong inference of scienter and that discount is "steep." *Id.* at *3. As the court firmly held, "[i]t is hard to see how information from anonymous sources could be deemed 'compelling' or how we could take account of plausible opposing inferences. Perhaps these confidential sources have axes to grind. Perhaps they are lying. Perhaps they don't even exist." *Id.* at *2. All of these problems similarly plague the Amended Complaint here.

Moreover, even before *Tellabs*, allegations attributed to a confidential witness had to be accompanied by enough particularized detail "to support the probability that a person in the position occupied by the source would possess the information alleged and . . . contain[] adequate corroborating details." *Daou*, 411 F.3d at 1115-16; *In re Siebel Sys., Inc. Sec. Litig.*, No. C 04-0983 CRB, 2005 WL 3555718, at *8-9 (N.D. Cal. Dec. 28, 2005). In this respect, it is telling that ***none*** of these supposed "witnesses" referenced in the Amended Complaint are alleged to have worked in Connetics' finance or accounting department, had any involvement in or familiarity with the preparation of its financial statements or earnings releases, or any understanding of how Connetics was accounting for reserves or recognizing revenue. *See In re U.S. Aggregates, Inc. Sec. Litig.*, 235 F. Supp. 2d 1063, 1075 (N.D. Cal. 2002) (rejecting confidential witness

allegations where none had first-hand knowledge of the company's accounting decisions); *In re Veritas Software Corp. Sec. Litig.*, No. C-03-0283, 2003 U.S. Dist. LEXIS 27480, at *16-19 (N.D. Cal. Dec. 10, 2003) (dismissing complaint involving a restatement where the witnesses did not have positions that would make them knowledgeable about the company's accounting); *see also Cal. Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 152-53 (3d Cir. 2004) (affirming dismissal where plaintiffs failed to "demonstrate how a former employee working in a customer service capacity would know that, nationally, 25% of Chubb's reserves were manipulated downward").[27]

In any event, plaintiff's allegations are conclusory and lack particularized allegations of fraud. Although plaintiff uses these witnesses to suggest, in one form or another, that Connetics allegedly shipped products to distributors that "exceeded the number of prescriptions being written" (*e.g.*, AC ¶¶ 112, 115(ii), 116, 117), no one identifies the particular products, when the shipments occurred, the extent to which supply exceeded demand, the amount of revenue involved, what reserves were taken, or whether the goods were returned. *See Ramp*, 201 F. Supp. 2d at 1067 (dismissing complaint where confidential witnesses did not provide specific facts about the recognition of revenue associated with the challenged practice); *Foundry*, 2003 WL 22077729 at *7 (statements by a confidential witness that "management was insisting that orders scheduled for shipment in the fourth quarter of 2000 be sent in September so that the revenue could be recognized in the third quarter" lacked sufficient particularity to state a channel stuffing claim); *Garfield*, 466 F.3d at 1265 ("Absent from these allegations are any particularized averments of fraud or scienter . . . . A general allegation that Individual Defendants promoted

[27] Instead, the anonymous sources referenced by plaintiff are variously described as a "manager" and "territory manager" of an unspecified aspect of Connetics for as little as "six months" (AC ¶¶ 116-17 (CW 5, 8)), as "sales" personnel (*id.* ¶¶ 55, 116 (CW 3-4, 6-7)), or involved in "marketing" or "toxicology" (*id.* ¶ 53 (CW 1, 2)). The job responsibilities of these witnesses are not described, and there is no reason to believe they would have knowledge of Connetics' accounting or financial reporting. *See In re Alamosa Holdings, Inc. Sec. Litig.*, 382 F. Supp. 2d 832, 855 (N.D. Tex. 2005) (holding that sales and marketing confidential witnesses were incompetent to support accounting allegations where "no allegations exist that confidential witnesses had any background in accounting, access to information that demonstrates a company-wide scheme, or communications with anyone" regarding the alleged improper accounting).

channel stuffing at a series of meetings does not establish scienter").[28]

Similarly, the witnesses' statements regarding the alleged difference between Connetics' internal sales forecasts and historical prescription data could not give rise to any inference of scienter even if any of the missing details had been alleged. *See* AC ¶ 112. Connetics' public disclosures expressly state that it forecasts future demand by using a number of variables, not just historical prescription rates.[29] In fact, by its nature, historical prescription rates reflect *past* sales. To predict future sales, management must necessarily predict the sales growth rate for each Connetics product. As demonstrated by its public statements, Connetics' products experienced sales growth, and Connetics grew its sales force to meet that growth.[30] Accordingly, there is nothing nefarious about management predicting future product sales that exceed historical prescription rates.

D. Plaintiff Has Failed To Allege Loss Causation As To The Financial Statements

Plaintiff's "financial statement" claim also fails because it has not alleged loss causation. Among other things, plaintiff must allege that the "share price fell significantly after the truth

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[28] Likewise, the allegations that "there were constant discussions" or that "it was common belief within the Company" that Connetics had overloaded its customers "in order to increase its quarterly earnings" or "meet Wall Street expectations" (AC ¶¶ 116-17) are insufficient because such general allegations about "common belief" and what unidentified employees "generally thought" cannot survive a motion to dismiss. *See Spectrum*, 461 F. Supp. 2d at 1309-10 (finding confidential witness' statement that "we all knew what was going on, we front loaded the stores in August and September 2004" lacked sufficient particularity to support a securities fraud claim).

[29] Connetics regularly disclosed that in assessing financial guidance,

> Connetics' management considered many factors and assumptions including, but not limited to, current and projected prescription information; sales trend data of the Company's products; the potential generic availability of, and competitive threats to, the Company's products; size, reach and call frequency of the Company's selling organization; status, timing and progression of the Company's development projects; current and projected spending levels to support sales, marketing, development, and administrative activities; and other risk factors discussed in Connetics' publicly filed documents.

See, e.g., Ex. 17 (Form 8-K); Ex. 20 (Form 8-K).

[30] *See, e.g.*, Ex. 13 (Form 8-K) ("Total revenues for the second quarter of 2004 increased 92%"); Ex. 14 (Form 8-K) ("Product revenues for the 2004 third quarter more than doubled . . . compared with . . . the comparable period last year"); Ex. 17 (Form 8-K) ("product sales for the first quarter of 2005 increased 79%); Ex. 19 (Form 8-K) ("during the second quarter 2005 prescriptions written for OLUX, Soriatane and Evoclin reached all-time quarterly highs").

became known" to the market. *Dura*, 544 U.S. at 347. Plaintiff has not and cannot do so. To the contrary, the absence of loss causation is readily apparent from the face of the Amended Complaint.

On May 3, 2006, Connetics announced, among other things, that it would be restating its 2005 financial statements (and potentially earlier periods) by approximately $8-9 million due to the insufficiency of reserves. AC ¶ 121. That announcement was made, as plaintiff admits, "after the market closed" on May 3. *Id.* ¶ 322. On that day, Connetics' shares closed at $13.76. Ex. 41 (stock prices). Following the announcement, Connetics stock price ***increased*** on May 4 to close at $14.20 on what plaintiff calls "heavy trading volume." AC ¶ 333(ii). Because plaintiff alleges that Connetics' shares "traded in an efficient market" and "promptly digested current information" which was immediately reflected "in the price of the Company's securities" (*id.* ¶ 336), plaintiff cannot show that the disclosures concerning Connetics' historical reserves and forthcoming restatement – which was followed by an increase in Connetics' stock price – caused any loss. *See In re Impax Labs Inc. Sec. Litig.*, No. C-04-04802 JW, 2007 U.S. Dist. LEXIS 723, at *16-18 (N.D. Cal. Jan. 3, 2007) (plaintiff failed to show loss causation where stock price rose after announcement); *In re GlaxoSmithKline PLC*, No. 05 Civ. 3751(LAP), 2006 WL 2871968, at *13 (S.D.N.Y. Oct. 6, 2006) (dismissing complaint where, as here, the complaint "fails to allege that a misrepresentation by Defendants, when revealed to the public, was the proximate cause of any loss suffered by Plaintiff.").[31]

Nor can plaintiff plead loss causation with respect to Connetics' July 10, 2006 announcement. As a preliminary matter, since that announcement was made ***after*** the class period, plaintiff cannot base any loss thereon. *See Powell*, 2007 U.S. Dist. LEXIS 36834, at *14 ("because the misrepresentations were not made known to the marketplace until after the Class Period, the decline in stock price has not been causally linked to the improper activities of the

[31] Plaintiff has apparently recognized this fatal flaw in its claim and, rather than candidly acknowledging the price of Connetics' stock on May 3, has tried to compare the stock price on another day (May 2) to the price on May 4. *See* AC ¶ 333(ii). Plaintiff, however, pleads no basis for such a contrived allegation, since the dispositive question is how the market reacts to disclosure of the relevant truth, which occurred after the market closed on May 3, 2006, not at some earlier time before the disclosure was made. *See Dura*, 544 U.S. at 342-43.

Defendant").

More fundamentally, however, plaintiff does not – and cannot – cite any previously undisclosed information in the July 10, 2006 announcement concerning Connetics' 2004 or 2005 reserves or financial statements. *See* AC ¶ 127; Ex. 21 (Form 8-K); Ex. 22 (Form 8-K). Rather, the July 10 press release discloses that Connetics did not expect to meet forward-looking financial expectations for the second quarter and full year of 2006, because it had decided to "ship below estimated prescription demand during the remainder of 2006" in order to reduce "average wholesaler inventory levels to approximately two months on hand by the end of 2006." AC ¶ 127. In addition, the July 10 press release merely reiterates the exact same information in the May 3 press release regarding reserves in 2004 and 2005. Ex. 22. As such, loss causation is utterly lacking. *See Dura*, 544 U.S. at 343 (it is not enough for disclosure to "touch upon" the subject of alleged misrepresentation in some way; rather, the disclosure must reveal the "relevant truth" to have "caused" the loss); *In re IPO Sec. Litig.*, 399 F. Supp. 2d 298, 307 (S.D.N.Y. 2005) (same).

Finally, to the extent plaintiff purports to base its claim on supposed "channel stuffing," loss causation is absent because plaintiff can point to no disclosure, either by Connetics or a third party, suggesting that Connetics had sold unwanted product to its customers in 2004 and 2005. *See D.E.& J. Ltd. P'ship v. Conaway*, 133 Fed. Appx. 994, 1000-01 (6th Cir. 2005) (no loss causation based on stock price drop on announcement of bankruptcy since filing did not reveal prior alleged misrepresentation); *In re Tellium, Inc. Sec. Litig.*, No. Civ. A. 02CV5878 FLW, 2005 WL 2090254, at *1 (D. N.J. Aug. 26, 2005) (no loss causation based on announcement of bad news that did not disclose defendants' fraud); *In re Avista Corp. Sec. Litig.*, 415 F. Supp. 2d 1214 (D. Wash. 2005) (dismissing complaint where disclosures that caused the stock price drop did not reveal prior misrepresentations).

VI. PLAINTIFF HAS FAILED TO PLEAD A CLAIM UNDER SECTION 20A

Plaintiff purports to assert an insider trading claim under Section 20A of the 1934 Act against Mr. Wiggans, Mr. Vontz and Mr. Higgins (but not Dr. Krochmal). AC ¶¶ 368-72. However, Section 20A requires, *inter alia*, an independent violation of the 1934 Act. *In re*

VeriFone Sec. Litig., 11 F.3d 865, 872 (9th Cir. 1993). Because plaintiff has failed to plead an underlying violation of Section 10(b), there can be no claim under Section 20A. *Id.*

The claim is also deficient because it is devoid of particularized facts establishing that these defendants sold Connetics stock on the basis of material non-public information. *See In re 3Com Corp. Sec. Litig.*, No. C-97-21083 JW, 1999 WL 1039715, at *3 (N.D. Cal. July 8, 1999). Plaintiff must allege particularized facts specific to each defendant, including "the times, dates, places, benefits received, and other details of the alleged fraudulent activity." *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993). Although plaintiff offers the general allegation that "defendants were in possession of non-public information" (AC ¶ 370), such catch-all pleading is no substitute for alleging "specifically what information [each defendant] obtained, when and from whom he obtained it, and how he used it for his own advantage." *Neubronner*, 6 F.3d at 670; *see In re Oak Tech. Sec. Litig.*, No. 96-20552 SW, 1997 WL 448168, at *12 (N.D. Cal. Aug. 1, 1997) (allegation that defendants "knew the adverse non-public information" was insufficient).

In addition, Section 20A only applies to persons who trade "contemporaneously" with the alleged insider. *In re HI/FN, Inc. Sec. Litig.*, No. C-99-4531 SI, 2000 WL 33775286, at *12 (N.D. Cal. Aug. 9, 2000) (Illston, J.) (quoting *Neubronner*, 6 F.3d at 670). Here, plaintiff does not even purport to identify any contemporaneous trades with Mr. Wiggans or Mr. Vontz. AC ¶ 371; *see HI/FN, Inc.*, 2000 WL 33775286, at *12 (generalized allegation of contemporaneous trade is "inadequate"). With respect to Mr. Higgins, plaintiff purports to identify his sale of 5,000 shares of Connetics common stock on April 19, 2005 (AC ¶ 371), but since that sale was made pursuant to a pre-existing trading plan under Rule 10b5-1 (Ex. 25 (Forms 4)), he could not have been "selling securities on the basis of material nonpublic information." *See Wietschner*, 294 F. Supp. 2d at 1117 (use of a 10b5-1 trading plan negates suspicion). In any event, plaintiff's failure to provide any specifics concerning the "inside information" allegedly possessed by Mr. Higgins at the time of the trade is fatal to its claim. *See Neubronner*, 6 F.3d at 670.

VII. PLAINTIFF HAS FAILED TO PLEAD A CONTROL PERSON CLAIM UNDER SECTION 20(a)

Because plaintiff has not pleaded a viable claim under Section 10(b), its control person

claim under Section 20(a) against Mr. Wiggans, Mr. Vontz and Mr. Higgins necessarily fails, and again, there is no such claim brought against Dr. Krochmal. *Paracor Fin., Inc. v. General Elec. Cap. Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996). The claim also fails because plaintiff has not pleaded facts showing that each defendant had the "actual power" or "exerted" influence over the controlled person with respect to the specific transaction or activity upon which the alleged primary violation was predicated. *See Durham v. Kelly*, 810 F.2d 1500, 1503-04 (9th Cir. 1987); *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1067 (9th Cir. 2003).

For example, plaintiff makes no attempt to explain how Mr. Higgins, as CFO, could be responsible for or control the Company's disclosures concerning Velac. Similarly, plaintiff does not explain how Mr. Wiggans and Mr. Vontz, as CEO and COO respectively, were responsible for or controlled Connetics' accounting for reserves or other items. *See Howard*, 228 F.3d at 1067 (plaintiff "simply points to [defendants'] general level of control but provides no specific indication that [they] supervised or had any responsibility for the preparation of financial statements"). It is not enough to allege their status as senior officers or claim that they signed SEC filings. *See In re Gupta Corp. Sec. Litig.*, 900 F. Supp. 1217, 1243 (N.D. Cal. 1994).

VIII. CONCLUSION

For the foregoing reasons, the Amended Complaint should be dismissed.

Dated: August 13, 2007

Respectfully submitted,

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